



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

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One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

July 18, 2003

WARNING LETTER

NWE-20-03W

FEDERAL EXPRESS

Joan Collagen, Co-Owner
Mayflower Natural Foods
dba Spredumms
740 Corporate Park
Pembroke, Massachusetts 02359

Dear Ms. Collagen:

On February 24, 2003 we inspected your seafood processing facility, located at 740 Corporate Park, Pembroke, Massachusetts. We found that you have serious deviations from the Seafood Hazard Analysis Critical Control Points (HACCP) regulations, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly your Crab Creole Cheese Spread has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must conduct or have conducted a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However your firm does not have a HACCP plan for your Crab Creole Cheese Spread to control the food safety hazards of *Clostridium botulinum* and pathogens. Your hazard analyses for all your seafood products may determine that you may require more than one HACCP plan, and that there may be additional hazards to control.
- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm did not maintain sanitation monitoring records for any of the eight (8) areas of sanitation required for the processing of your Crab Creole Cheese Spread.

Based on observations we made during the inspection and a review of your label, your Crab Creole Cheese Spread is also misbranded:

- The Crab Creole Cheese Spread product is misbranded within the meaning of Section 403(c) of the Act (21 USC 343(c)), in that it is an imitation of another food and the label fails to include, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated as set forth in 21 CFR 101.3(e). Specifically, because the product actually contains imitation crabmeat instead of actual crabmeat as the main ingredient, the word "imitation" must appear before the word "crab" in the product name.
- Your Crab Creole Cheese Spread is also misbranded within the meaning of section 403(i)(2) of the Act (21 USC 343(i)(2)) because the product is made of two or more ingredients, and the label does not bear the common or usual name of each ingredient, as required by 21 CFR 101.4(a)(1). Specifically, the ingredient statement on your Crab Creole Cheese Spread does not include the imitation crabmeat and [REDACTED] ingredients.
- The Crab Creole Cheese Spread is further misbranded under section 403(i)(2) of the Act because the ingredient statement fails to bear all the component ingredients of several main ingredients which themselves contain two or more ingredients, as required by 21 CFR 101.4(b)(2). For example, the product contains cream cheese, cheddar cheese, imitation crab, and [REDACTED] however, the ingredient statement does not include the components of each of these ingredients. This requirement may be met either by parenthetically listing the component ingredients after the common or usual name of the main

ingredient, or by listing the component ingredients without listing the common or usual name of the main ingredient itself. Under the first alternative, the component ingredients must be listed in descending order of predominance within the parenthesis; and under the second alternative, the component ingredients must be listed in descending order of predominance in the finished food. Declaration of the milk in the cream cheese and cheddar cheese, the fish ingredients in the imitation crab and the ingredients in the [REDACTED] is of particular concern because they are allergenic substances. For sensitive individuals, the presence of allergens in food is potentially life-threatening


We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operation.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation, such as a completed HACCP plan, or other useful information that would assist in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,


Gail F. Costello
District Director
New England District